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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,262

09/12/2003

John Coogan

98103.00017

7783

7590

10/26/2006

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/661,262

Applicant(s)

COOGAN ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The amendment and remarks filed 6/26/06 are acknowledged.

Claims 1-9, 11-13 and 17-19 are pending.

### *Response to Arguments*

Applicant's arguments with respect to claims 1-9, 11-13 and 17-19 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, 9, 11-13, and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims recite a method for treating a complex fluid or a nucleic acid within a complex fluid by subjecting said fluid to a monochromatic excimer-based, non-laser light source within a given range of wavelengths, wherein the complex fluid has at least two components that are responsive to light energy and said light source is effective to preserve one component while exciting the other component. The phrase "complex fluid" encompass blood products, pharmaceuticals, injectable solutions and vaccines (all claimed) as well as a huge number of biological and non-biological fluids having at least two components that are light sensitive for which no written description has been provided. Moreover, the description of blood products, pharmaceuticals, injectable solutions and vaccines does not provide a

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representative sample of biological and non-biological fluids having at least two components that are light sensitive encompassed by the claims, given the huge variation in physical, structural, chemical properties and sources of said fluids that are encompassed by the current broad claim language. Because the claims encompass a multitude biological and non-biological fluids having at least two components that are light sensitive that are neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

Claims 1-9, 11-13 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a complex fluid or DNA within a complex fluid by subjecting said fluid to a monochromatic excimer-based, non-laser light, silent discharge plasma-generated light source within a given range of wavelengths, wherein the complex fluid has at least two components that are responsive to light energy and said light source is effective to preserve one component while exciting the other component wherein the light source is maintained at an ambient temperature, does not reasonably provide enablement for a method of treating a complex fluid by subjecting said fluid to a monochromatic excimer-based, non-laser light source within a given range of wavelengths, wherein the complex fluid has at least two components that are responsive to light energy and said light source is effective to preserve one component while exciting the other component wherein the light source is maintained at any temperature. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification asserts that the claimed method represents an improvement over the prior art because said method allows for the photo-treatment of opaque fluids having light-sensitive components wherein the light affects only one of the components. However, the specification also discloses the necessity of using SDP-generated UV light and maintaining an ambient temperature at the light source :

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"According to the present disclosure, light emitting, i.e., photon-producing, gas sources are contained within the bounded volume of annulus 206. Preferred light emitting/photon-producing gas sources are "excimers," as are known in the art. Excimer sources (also called "excited dimers") driven by dielectric barrier discharge offer a unique, advantageous set of capabilities for fluid treatment regimens according to the present disclosure: operation at ambient temperature, discretely tunable monochromatic output, variable emitting areas, and high germicidal UV output per lamp." (p. 28)

Similarly, Coogan (2005) discusses the use of silent discharge excimer lamps to inactivate microorganisms within complex, low-optical-quality fluids. Coogan discloses that silent discharge plasma (SDP)-generated UV light, wherein one or both electrodes are covered with dielectric layers that isolate the electrodes from the gas are optimal to effect inactivation of microorganisms in opaque fluids. Coogan teaches that it is critical to operate the excimer lamps at a low temperature in order to effect pathogen inactivation in order to preserve the therapeutic function of blood products (p. 1513, left column, 1<sup>st</sup> full paragraph). Coogan also discloses that "Without the dielectric layer(s), the application of an electric field of sufficient magnitude across an atmospheric pressure gas gap results in the formation of a few localized arcs..." and that the addition of a dielectric and the application of an alternating high voltage allows for the substantial generation of a large number of microdischarge needed to fill the reactor volume (p. 1512, left col., 2<sup>nd</sup> full paragraph).

Therefore, the necessity of using SDP-generated UV light and maintaining an ambient temperature at the light source appear to be critical to the invention. However, the as-filed specification provides no disclosure as to how to achieve the claimed method without using SDP-generated UV light and maintaining an ambient temperature at the light source. Hence, the claims encompass a method of photo-treating a complex fluid by subjecting said fluid to any monochromatic excimer-based, non-laser light source within a given range of wavelengths, wherein the complex fluid has at least two components that are responsive to light energy and said light source is effective to preserve one component while exciting the other component wherein the light source is maintained at any temperature. Because of the huge variation in light sources, combined with the fact that the specification provides only a single type of light source, water-cooled SDP-generated UV light that is excimer-based, non-pulsed and non-laser to

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achieve the desired selective photo-treatment, the skilled artisan would expect to have undertake an essentially trial and error process, with no guidance from the specification as to the expectation of success or failure, to determine which of the numerous light sources and working temperatures encompassed by the claims is amenable to the techniques disclosed herein. Such a trial and error process clearly amounts to undue experimentation.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 1-9, 11-13, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 5 and 13 are rejected because the used of the term "based" in the phrases of an "excimer-based" light source and a "blood-based product" render the phrases vague and indefinite because it is unclear what the extent of the basis of the excimer or the blood have in the light source and product, respectively.

Claims 6 and 9 are rejected because the term "involves" is vague and indefinite. The term "involves" implies additional steps in the process and it is unclear if those steps are necessary to the claimed methods.

No claim is allowed.

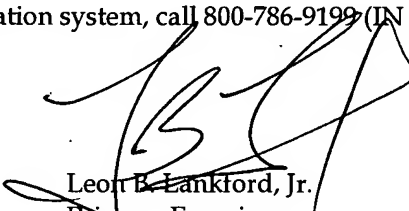
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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